UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE, S.A. and ROCHE PALO ALTO, LLC,

Plaintiffs,

-vs-

DR. REDDY'S LABORATORIES, LTD., et al.,

Defendants.

CIVIL ACTION NUMBER:

11-3962(MLC)

MARKMAN HEARING

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
September 23, 2014

B E F O R E: THE HONORABLE MARY L. COOPER
UNITED STATES DISTRICT JUDGE

Certified as True and Correct as required by Title 28, U.S.C., Section 753

/S/ Regina A. Berenato-Tell, RMR, CRR, CCR

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TRENTON, NEW JERSEY, TUESDAY, SEPTEMBER 23, 2014, 1:30 P.M.

(In open court.)

THE COURT: Good afternoon, everyone. Welcome.

Here we are in Helsinn versus Dr. Reddy, Sandoz, and Teva with the lead action number 11-3962. And I'll take your appearances in the order of the caption. Everyone else may be seated.

MR. LIZZA: Good afternoon, your Honor. Charles M. Lizza of the Saul Ewing firm, and with me is my partner William C. Baton. And I'll have the Paul Hastings colleagues identify themselves.

MR. DITTMANN: Good afternoon, your Honor. Eric Dittmann from Paul Hastings on behalf of Helsinn.

MS. NI: Good afternoon, your Honor. Angela Ni from Paul Hastings on behalf of Helsinn.

THE COURT: Fine. Thank you.

MR. WONG: Good afternoon, your Honor. Jovial Wong from Winston and Strawn on behalf of the Teva defendants.

MS. TARANTINO: Good afternoon, your Honor. Mayra Tarantino from Lite, DePalma, Greenberg, also on behalf of Teva.

MR. SENDER: Good afternoon, your Honor. Stewart Sender from Budd Larner on behalf of Dr. Reddy.

MR. IMBACUAN: Good afternoon. Michael Imbacuan from Budd Larner on behalf of the DRL defendants.

MR. D'AMORE: Good afternoon, your Honor. Matthew D'Amore from Morrison and Foerster for Sandoz.

MR. ABRAHAM: Hello, Judge. Eric Abraham from Hill Wallack, also on behalf of Sandoz. And I would like to introduce to the Court Ms. Josephine Liu, who is in-house patent counsel for Sandoz, also present in the courtroom.

THE COURT: Welcome. Welcome one and all. Good. Okay. I have briefs. It looks as if defendants consolidated your briefing for this claim construction hearing; is that right?

MR. WONG: That's correct, Your Honor.

THE COURT: And the one issue that I have been told we have to take up this afternoon is whether this preamble language after the word "formulation" in Claim 1 of the '219 patent is limiting or not, right?

MR. DITTMANN: Correct.

THE COURT: Okay. It looks like, Mr. Dittmann, you're poised to present.

MR. DITTMANN: Yes, I am, Your Honor.

THE COURT: Go right ahead.

MR. DITTMANN: May I approach, Your Honor? I have copies of slides.

THE COURT: Oh, sure. Thanks.

MR. DITTMANN: Good afternoon, again, Your Honor. My plan for this afternoon is to provide a very brief background

discussion on some relevant items concerning this claim construction dispute and then to jump right into the issue, as you just mentioned, whether or not this disputed preamble language limits the claims. And from a high level perspective there's really two fundamental reasons why this language is limiting, and one is that it provides antecedent basis for the words "said formulation" in the body of the claims.

THE COURT: Now hold on. I don't mean to stop you so fast, but the other side agrees that up to the word "formulation" in the preamble everybody's fine with it to be limiting, and, so, the disputed preamble language comes after the word "formulation" in the preamble.

MR. DITTMANN: Yes, and I'm going to go through that specifically to show you where there's agreement and where there's disagreement, and I'll explain to you hopefully why we think the language should be found limiting.

THE COURT: I'm following you.

MR. DITTMANN: Great. And the second independent basis is that there was -- the intrinsic evidence makes clear, including through clear reliance during prosecution, that this language serves as a limitation of the claims.

So, very briefly, Your Honor may recall from our last Markman hearing that this case -- these patents are directed to what are known as setrons. They are used to treat emesis, otherwise known as nausea and vomiting. And palonosetron is

the specific setron that is used in the formulations of the patents-in-suit.

Palonosetron is marketed in the United States as a formulation for intravenous administration under the name Aloxi®. And Aloxi® in the U.S. is specifically used to treat chemotherapy-induced nausea and vomiting, which as we've explained previously, can be a critical aspect of cancer treatment in ensuring that patients can continue to take what can be very hard medicines in the form of chemotherapy and withstand them.

The patents-in-suit in this case -- there are four of them -- we're focusing only on one today, the '219 patent in red. All four of these patents are related. They stem from the same priority application. They have nearly identical specifications, and for purposes of today's discussion there's no differences that are relevant. And all of them cover the Aloxi® intravenous formulation.

THE COURT: All of them cover intravenous, all four of these patents?

MR. DITTMANN: Yes.

THE COURT: Okay.

MR. DITTMANN: Now, I want to talk a little bit about this disclosure of the '219 patent. Defendants have some statements in their papers about the meaning of some of the efficacy-relating statements in the '219 patent, and while the

precise meaning of these statements are not necessary to resolve today's claim construction dispute, they're helpful, we think, to understand and provide support for why some of the language is limiting.

So, to start with, the patents make clear that the formulations serve two objectives. One, pharmaceutically stable. We talked about that at length two years ago at the last Markman hearing. That's not for today.

The second aspect that is relevant today is that they can be used to treat emesis, including what I'll refer to as CINV, chemotherapy-induced nausea and vomiting. As we can see from the abstract, the present invention relates to shelf stable liquid formulations of palonosetron for reducing chemotherapy- and radiotherapy-induced emesis.

So, as we'll continue to go through the patent disclosures I wanted to keep this in mind that there's really two aspects to what's being discussed here, that these formulations are both shelf stable and they're able to treat this condition, CINV. And, in fact, one of the objects of the invention is to provide a formulation of palonosetron with increased pharmaceutical stability for preventing and/or reducing emesis.

THE COURT: And the word "for" there modifies the word "formulation." It is not modifying "stability."

MR. DITTMANN: Correct. That's what a formulation, a

medicament is for; it is to treat a condition. It is not to -- should not sit on a shelf and remain stable.

THE COURT: Right. Exactly.

MR. DITTMANN: So the summary of the invention -- in fact, the very first aspect of the invention that's discussed is a series of discoveries that support a surprisingly effective treatment for prevention of emesis using palonosetron. And it continues, "The inventors have discovered that...only 1/10th of the amount of other previously known compounds," other setrons that are mentioned in the patent, but do not contain palonosetron, you can use much lower amounts of palonosetron to treat emesis. And that's one aspect of this invention.

And that's made clear...

THE COURT: Can I just stop you there for a second?

MR. DITTMANN: Sure.

THE COURT: In one aspect the inventor -- I'm just reading from what is in the summary on the board. "The inventors have discovered that formulations, which include the active ingredient palonosetron require in some instances only 1/10th of the amount of other previously known compounds." So, this invention doesn't say, Oh, we came up with the surprising discovery that we can use one-tenth as much palonosetron if we formulate it this way and we can still succeed with this treatment, no.

MR. DITTMANN: What they're saying is we're using very low amounts, much smaller than the amounts used in other setron products, you're correct, that known in the prior art. And what they're saying is it is surprising that this molecule palonosetron can be used at such low amounts relative to the other setrons, and, again, it is important for treating emesis, and we're talking about the amounts of palonosetron. There's no discussion here of stability. That comes later. That's another aspect of it.

It turns out, Your Honor, that low amounts of palonosetron are both beneficial for stability, and they also are able to treat emesis. And you'll hear about this more as this case progresses, but that is really the fundamental aspect is that it was surprising the stability that was seen, but it was also surprising that there was efficacy at all, given the prior art disclosures about palonosetron. We don't need to get into the details of the prior art disclosures regarding the amounts of palonosetron, but all I wanted to illustrate was this invention is clearly talking about efficacy aspects on the one hand and stability on the other.

Further on in the body of the specification, which was cited in our briefs, there's some more disclosure, again, focused on the efficacy aspects of this invention, and here, again, we see the comments about the lower amounts of palonosetron to treat emesis, and then it continues and talks

about these lower dosages that can be used and administered intravenously. And an example that's provided is 0.25 milligrams of palonosetron, and that example is exactly what is specified in the claims-in-suit and, so, here, once again, we're clearly disclosing in this patent that 0.25 milligrams of palonosetron is effective or can be used to treat emesis, including CINV.

Now, here what we have is the claim setting forth the disputed preamble language, and what I have done here is the highlighted language is what the parties are currently disputing. There is no dispute, as I'll get to in a minute, about this language, and the reason that I'm highlighting these two terms, as I'm sure Your Honor is familiar with by now, is that plaintiffs contend that one basis -- not the only basis but one basis -- for saying that the disputed preamble language is limiting is that this preamble language should be taken as a whole. It is clearly describing and modifying the word "formulation." Just because some words come before and some come after, it doesn't change the fact that they're describing the formulation.

THE COURT: That's what you're saying?

MR. DITTMANN: That's what we're saying.

THE COURT: Yes.

MR. DITTMANN: But I'm saying that's one basis. There are other bases that I'll cover as to why this language

is limiting. And, again, this is very briefly setting forth the parties's positions that the highlighting language we just saw plaintiffs say it is limiting; defendants say it is not.

THE COURT: Go back to that slide, would you?

MR. DITTMANN: Sure.

THE COURT: Okay. If the Court finds that the disputed term is a limitation in whole or in part and should be construed then they still don't need to be construed --

MR. DITTMANN: Right.

THE COURT: -- because they have their ordinary meaning?

MR. DITTMANN: Everybody agrees they have their plain meaning.

THE COURT: Okay.

MR. DITTMANN: Now, before we get into the merits of whether this language is limiting or not, I did want to pause and posit that we're still scratching our heads over why this dispute is being raised by defendants. We're now in the middle of expert reports. We have received the second round from both parties submitted last week, and nothing -- and I have reviewed the reports very carefully -- nothing I see sets forth any argument that depends on defendants prevailing in their position here. In fact, the only thing I can see is the defendants are stating in their brief that they will assert a written description defense if plaintiffs's position is

adopted.

THE COURT: An enablement, I think, isn't that what they said?

MR. DITTMANN: It is a written description argument. There is a footnote at the bottom of the slide.

THE COURT: Lack of written description. Yes. Page 13, Footnote 12 of their reply brief.

MR. DITTMANN: In all honesty, Your Honor, we don't expect to see this defense at trial, but, nevertheless, it has been stated to be dependent on plaintiffs's construction being adopted, not their own. But more than that, we don't -- we have put in our briefs a number of times we don't see how this dispute matters. The parties's experts don't seem to think that matters. Defendants, nevertheless, raised this issue. We believe that it is clear that this language is limiting, and we're, frankly, concerned about the mischief of, well, all of a sudden now there's a Markman ruling, and they're going to make new arguments, even though we think they would be untimely at this late stage, there's no reason for us to agree that this language is not limiting when it is very clear that it is. And I'll review that.

THE COURT: I don't think I ever heard of that kind of scenario before. Every time I come out for a Markman hearing it is because the parties have some notion of how that's going to play into the strategy of the rest of the

case. They don't tell me what it is usually. At least they tacitly agree this matters, it matters or else they wouldn't be putting us through this exercise of claim construction on it.

Go ahead. It is your presentation.

MR. DITTMANN: So to begin with, defendants place a lot of reliance in their briefs on legal principles, and including this as an example of one that generally the preamble does not limit the claims. And we see variance of that throughout their brief.

But I want to start off with the notion to correct any misunderstanding that that does not apply in this case. Initially defendants took the position during the meet and confer process that the entire preamble was not limiting, and they said every part of it is not limiting. After the meet and confer process was concluding on the day that we were submitting joint claim construction charts they came in and changed their position and said, Oh, wait, no, this language, "pharmaceutical single-use unit-dose formulation" is limiting, but the rest is not.

So, we have a situation where the preamble is limiting by defendants's own admission, so this is not -- this is a case where the preamble is limiting. So resort to general principles is really not helpful to defendants. And we have to look at the facts. And I'll also explain, if it becomes

necessary that, in fact, the "single-use unit-dose" language that defendants claim to be the structural aspects of this preamble, in fact, is not. You can just see by the word "single-use" it is referring to how you use these formulations. "Single-use" refers to the fact that it is administered once to a patient and discarded.

And, so, putting that aside, though, the fundamental point that I want to make is these sort of general principles about preambles generally not limiting do not apply in this case because we have already all agreed that this preamble does at least limit in part.

So, then getting to the specifics, again, as I mentioned earlier, plaintiff's position is the preamble is one limitation. And it describes the formulation. And we don't think it is proper to break it up into parts, but that is what defendants have done. They have sort of carved out the front part of the preamble and said it is limiting, so that is not in the case any longer. And they have made arguments about two other parts of that preamble phrase, so I'm going to deal with them...

THE COURT: But you don't have any authority for the notion that a long run-on clause consisting of several phrases has to be interpreted as a single limitation.

MR. DITTMANN: I agree it doesn't have to be, Your Honor. Certainly, if there is a long list of phrases that

don't relate to the formulation, but here everything, as I'll explain, relates back to the formulation and describes the formulation.

And, certainly, with respect to this first phrase "for intravenous administration to a human," frankly, we don't see much of a dispute here. I'll go through the reasons for that. And the first one is that defendants's responsive brief, they concede that intravenous preamble language from the original patents-in-suit, the '724, '725, and '424 patent they admit that those are limiting. And as I'll explain to you that phrase "intravenous" in the preamble of the other patents has the same meaning as "for intravenous administration." There's no distinction between those two phrases. And, in fact, the defendants's experts have provided testimony admitting this.

The second point is that "for intravenous administration" provides structural antecedent basis for "said formulation" in the body of the claims. And I'll explain that, but it is sort of common sense; when you're putting something directly into your blood, there are special requirements to make sure that patients aren't harmed, there aren't irritations, there are special considerations for intravenous administration formulations, and, therefore, that has an effect.

THE COURT: Also, I notice that the specification, which I don't know how common it is to how many other patents,

mentions both "intravenous" and "oral," but when we get to the claims we only have two independent claims here in this patent, and they're both clearly for intravenous.

MR. DITTMANN: Yes. And, your Honor may recall in our opening brief you went through a very long summary of the prosecution where some oral prior art formulations were distinguished because the claims of these patents are focusing on the I.V. aspect. This is about I.V.

And the last independent basis is there is some relevant prosecution history that I'll discuss that makes clear that intravenous is a limitation of these claims.

So, again, the first point here is that, again, we had a summary of prosecution histories from four separate applications, all of them the family that led to this patent, the '219 patent, and over and over again the patentees distinguished oral prior art solutions as not being intravenous.

And now defendants don't contest this clear reliance. They say we agree. "Intravenous solution," "intravenous isotonic solution" and the like from these various patents are all limitations, and those are preamble -- those are in the preamble. And they say it is because it affirmatively recites essential structure, and we agree, "intravenous" does convey essential structure, as I just mentioned.

But the issue here is that when you look at what

defendants, for example, Claim 1 of the '724 patent, what they concede to be limiting is indistinguishable from what we have in our claim of the '219 patent. That is because "intravenous" is Latin for inside the vein. It is talking about what you do with a formulation. You're putting the formulation inside the vein of a human. And it is a prepositional -- the prepositional phrase "for intravenous administration" is the same thing as the use of "intravenous" as an adjective. There's no difference.

And, frankly, defendants's experts wouldn't get up here and tell you anything differently, and we know that because we have their testimony, and I can walk you through that. For example, Dr. DeLuca, one of defendants's experts in one of his expert reports states that "intravenous solution is a parenteral liquid solution dosage form that is administered through injection into a vein of the human body." That is essentially saying what I'm saying, that they're the same. An intravenous solution is administering the solution through a vein intravenously.

THE COURT: Nobody really disputes that we're talking about medicine for a human being, right?

MR. DITTMANN: We certainly don't, Your Honor.

THE COURT: I mean, you can have an intravenous veterinary solution, I'm sure?

MR. DITTMANN: That may be, but we think it is very

clear, again, from the claims that we're talking about administering to a human, and that's the subject that needs chemotherapy-induced nausea and vomiting treatment. I'm not aware of any animals that undergo chemotherapy.

THE COURT: Yes, they do.

MR. DITTMANN: Do they?

THE COURT: They absolutely do.

MR. DITTMANN: I'm not aware of at least antiemetics and these sort of palonosetron solutions being used, but, nevertheless, points well taken.

Now, we have Dr. DeLuca separately stating and summarizing one of the prior art articles, the Tang reference, he says, "The Tang discloses the use of an intravenous solution of palonosetron to treat PONV." "In particular, Tang disclosed that each dose of medication used was an isotonic sodium chloride solution of palonosetron administered intravenously." This is not debatable. These are the same -- this means the same thing, these two sets of words.

Dr. Frame made a similar admission. I won't belabor the point with respect to another prior art reference, and Dr. Kirsch, another one of defendants's experts, he equates "administered through intravenous administration" to "an intravenous formulation."

What we have is over and over again, and if anything more was necessary, even last month defendants's expert Dr.

DeLuca sets forth Claim 1 of the '219 patent, and he summarizes his opinions that saying, "it would have been obvious to develop an intravenous solution with common components in the prior art." Again, "intravenous solution" is no different than "for intravenous administration."

So, that's we think -- number one, we think defendants's admission puts this issue to bed. But even if there was some argument to say that these words had any slight difference in meaning defendants say that, Well, you can't use the prosecution for a word like "intravenous" and then apply it to a different term like "for intravenous administration." They have to be the same claim language is what defendants say, but that's not the law. The Federal Circuit has made clear that the proper inquiry in such a circumstance is whether the scope of the claim limitation is substantially the same in the subsequent application as it is, for example, in the parent application.

And the Masco case we cited in our opening brief provides one example; in this case the parent application had the term "positively driving" as part of a means plus function, and statements regarding that claim term was used to construe the phrase "to drive." Just one example. They don't have to be exactly the same language. They have to be either the same or substantially the same.

Now, bringing us back to our point about antecedent

basis, defendants provide a test where they say, Well, the antecedent basis in this case is if it's the structural part of the preamble they say that's what comes in through this antecedent basis. But, again, there really can't be a legitimate dispute that when a person of skill in the art sees "for intravenous administration to a human" that conveys certain structural requirements for the formulation. Not only that it be isotonic and sterile like the claims already require, but that it be free of pyrogens, these substances that can raise body temperature and cause fever. It also has to be free of particulate matter. This is very different than if you're taking something and ingesting it orally and you have the benefit of your low pH of your intestinal system in your stomach to handle these formulations. So we think even if that's the test, that's readily met here.

Now one last point, your Honor, and this one is important to keep in mind, as well; the word "isotonic" everyone agrees is a limitation of these claims. No one disputes that "isotonic" is not limiting. And I'm going to show you that in the parent application for this patent that "isotonic," that claim term was described to mean to refer to intravenous formulations, and I'll show you that now. In an appeal brief in the parent application in distinguishing, once again, oral formulations --

THE COURT: This is appealing to the Patent Office

Board of Appeals or something?

MR. DITTMANN: Correct.

THE COURT: Go ahead.

MR. DITTMANN: So in that appeal brief -- and we'll come back to this brief later for a different reason -- but in that brief we're distinguishing oral formulations, and in making that argument the applicants say that, "this ignores the requirements of the claims for isotonicity," which is, again, a claim requirement to the '219 patent, "which is a requirement only for intravenous formulations."

So, the point is this: We think it is crystal clear that the preamble phrase "for intravenous administration" is limiting, but even if we're wrong it still is a requirement through the word "isotonicity" in the body of the claim, so even if the defendants prevailed on the preamble point it is still a limitation of the claims either way.

THE COURT: You mean to be intravenous is necessarily implied by this word "isotonic."

MR. DITTMANN: And that's exactly what the applicants are saying in this prosecution document. They tell the Patent Office our claims require isotonicity; that distinguishes us from oral because isotonicity is a requirement for intravenous formulations. If this were a case, your Honor, where we were alleging the defendants's oral formulations somehow were infringing this would be the sort of thing where it would

become frivolous for us to say that "intravenous" is not a requirement of the claims. I submit for at least that reason it has to be a limitation here.

"To reduce the likelihood of CINV," that's the last part of this preamble phrase. And there are two basic points here, as well. Like what we just saw with "intravenous" this phrase was clearly relied upon during prosecution, including to distinguish the prior art. And the phrase is also a fundamental characteristic of "said formulation" in the body of the claims.

Now, very quickly, again, going back to the point about you can't rely on broad general principles, the defendants's statement about generally limiting -- not limiting when it's in the preamble, there's an exception that unless there's reliance in the prosecution. We have cited the Catalina point just as defendants did for this, and it makes clear that clear reliance during prosecution can render preamble language limiting. And in this case they mentioned the example of distinguishing prior art, but as I'll get to in a moment, you can also distinguish -- or you can also rely on preamble language to get over a 112 rejection, as well, and that causes the language to be limiting.

THE COURT: I get tired of remembering those subsections.

MR. DITTMANN: 112 is the disclosure requirements

that the claims have to provide a written description of the invention and enabling disclosure, amongst some other requirements, but for purposes of today we can talk about enablement since that is what happened in the parent applications.

So, I'll try and go through this relatively quickly because we have set this forth in our papers, your Honor, but to boil it down --

THE COURT: I think the new version of 112 actually gives us subparagraphs.

MR. DITTMANN: Which is nicer. A little bit more convenient.

The parent application, the '724 patent, again, this is the original parent application that ultimately led to the '219 patent, this claims that were originally filed were rejected because they had this language "preventing emesis." The examiner didn't like that and said, you know, while you're enabling for reducing, I don't like "preventing."

First of all, there's no point in the examiner rejecting those claims, unless they mean something and they limit them, but putting that aside, what the applicants did is they removed that language that the examiner didn't like and they put in a virtually identical preamble language to what we're talking about today, "reducing the likelihood of emesis."

THE COURT: And they put it in the preamble?

MR. DITTMANN: They put it in the preamble. Right.

THE COURT: So, the examiner was quibbling about the preamble?

MR. DITTMANN: The examiner is making clear that the examiner considered the preamble to limit, otherwise there would be no reason to reject those claims. If it is not a limiting preamble it doesn't matter for purposes of 112. But even as importantly, the applicants come and put this language in the claims, which, again, is nearly identical to the language we're talking about in the '219 patent, and they say the claims are directed towards reducing emesis or reducing the likelihood of emesis. And, so, this claim amendment and argument to overcome a 112 rejection, we submit, is one reason to find the nearly identical language "to reduce the likelihood of CINV" to be limiting under the Fantasy Sports case that we cited.

This same exact amendment and arguments were made in two other related applications. Exact same language was made, you know, was submitted. The amendments were made. The arguments were made multiple times, and the examiner relented, and the 112 argument was overcome for those reasons.

Now, the defendants they really don't quibble with the principle that if you overcome 112 using the preamble language an argument that it can be limiting; they say, oh, we miscite

the Fantasy Sports case because in Fantasy Sports only the word "computer" was found limiting. The rest of it "for playing football based upon actual football games" was not.

Well, first we'll put aside that they seem to be trying to make an argument that only structural limitations can be limiting when you overcome a 112 rejection, but let's put that aside and imagine that defendants are correct about that point, which we don't agree with. Fantasy Sports made it crystal clear that the entire phrase "a computer for playing football based upon actual football games," that phrase constitutes a limitation. Defendants cite to different parts of the opinion referring to the, quote, "computer limitation." It is clear that's shorthand for the entire preamble phrase that the Court -- Federal Circuit expressly found limiting. But, again, that's just point number one.

The more important point is that even if you applied defendant's test that, well, they said only the "computer" language was amended. That's the only part they say was amended, and that's important for purposes of what's limiting. If you apply that test to our claims, again, what was amended is "reducing the likelihood of emesis," exactly what we're talking about except for, of course, emesis in our case is a specific type of CINV. So, defendants make the argument that, well, when you get a 112 rejection over preamble language you can just delete the preamble language, and you can obviate it

that way, and that may be true, but the fact that the applicants didn't do that and they amended the language to overcome the rejection shows, proves that it is a limitation.

Defendants make a separate argument relating to these parent applications, and, by the way, I just want to pause for a moment on this that defendants when it comes to intravenous preamble language they say it has to be the exact term in order for the parent prosecution to matter. But when we get to the "reducing the likelihood of emesis" language they have no trouble with equating "reducing the likelihood of emesis" with "reducing the likelihood of CINV." I think that's inconsistent. But putting that aside, they rely on this appeal brief, and their argument is that, well, that because "reducing the likelihood of emesis" doesn't appear --

THE COURT: You lost me. Actually, you're talking a little bit fast for purposes of an on the record session.

MR. DITTMANN: My apologies. I'll slow down.

THE COURT: We have the world's best court reporter here taking down every single word perfectly, but sometimes I get a little lost.

MR. DITTMANN: Please feel free to slow me down any time.

THE COURT: Okay.

MR. DITTMANN: So I want to just first make the point that remember earlier defendants's argument about intravenous.

They say the word "intravenous" is different than "for intravenous administration," and because of that difference they say you can't rely on prosecution statements relating to "intravenous" to apply to a different claim language "for intravenous administration." They make that argument. I have explained why that argument is not correct under the law. But I simply want to point out that when it comes to the separate preamble language "reducing the likelihood of emesis" they're attempting to use prosecution statements relating to that claim language, that preamble language that is different from the preamble language in the '219, they're using it affirmatively now to say, well, this proves that this is not a limitation. So there is inconsistency in their positions. Either the parent prosecution is relevant if it is similar claim language or it is not.

But, more importantly, defendants's reliance on this appeal brief lists -- and I want to explain what their argument is just to make sure we're all clear on this. They say that because the applicants did not include in this list here, did not include "reducing the likelihood of emesis" as one of the claim formulation features that that proves that "reducing the likelihood of emesis" is not a limitation.

THE COURT: Of the '219?

MR. DITTMANN: Of the '219, even though this is a statement from a previous application, but, again, putting

that aside, the M.P.E.P. is very clear that this summary of claimed subject matter that has to be provided, it only relates to subject matter of the claims involved in the appeal. It doesn't say every single claimed subject matter has to be summarized. It is what's involved in the appeal, and this part was not quoted in defendant's briefs, and we wanted to make sure this was clear that it has to be involved in appeal, and we just went through that the "reducing" preamble language, "reducing the likelihood of emesis" that was no longer at issue because they had overcome the examiner's rejection. There's no need to talk about that limitation when it wasn't relevant to an objection that was being discussed in this particular appeal.

And, frankly, defendants's Markman arguments from earlier in this case we think was correct. They said, "The claims of the asserted patents," these original '724, '725, and '424 patents "are directed to pharmaceutically stable intravenous palonosetron formulations that can be used for reducing or reducing the likelihood of emesis." We think that's correct.

Now, there's an independent basis for finding this language in the '219 patent limiting, which I think is very clear. This is from the '219 prosecution itself, the application that issued as a '219 patent. It is in examiner interview summary, so it is the examiner writing what was

discussed with the applicants, and it identifies --

THE COURT: Is this the last thing that happens in this prosecution history before the patent is approved or is there more?

MR. DITTMANN: I believe this was -- yes, it was.

THE COURT: Frequently the interview is the last exchange between the parties before the issuance notice is sent. Would that be the case here?

MR. DITTMANN: It can be.

THE COURT: No, here.

MR. DITTMANN: In this case, yes, this was at the end of the prosecution. But, also --

THE COURT: See, I have been given only portions of the file history, and that always leaves me a little bit --

MR. DITTMANN: Right. How much is this in the volume of paper?

THE COURT: That always leaves me just a little bit unsure of at what stage what was being discussed. But go ahead. I rely on these parties, you and your adversaries, to give me the pertinent portions of any of these histories, and I don't ask you to give me the whole file wrapper.

MR. DITTMANN: Some of them can be so huge. I don't think you would want them.

THE COURT: I know.

MR. DITTMANN: But, again, this prior art being

discussed, this is -- it includes Tang, and, by the way, the '219 prosecution was relatively small because there was a lot of prosecution activity in the original patents. So, you know, this again is a more different way of claiming this Aloxi® formulation, so --

THE COURT: Could I just stop you there and ask: It never is clear to me how so many patents get issued for, basically, you know, very, very similar facets of pharmaceutical formulations or uses. And here in this case we're going to be at trial, we're probably still going to be hearing about four patents, the ones that we have listed and you tell me they're all for intravenous forms of the same drug, Aloxi®, palonosetron. So, you know, in what way these patents differ and are similar I don't know.

MR. DITTMANN: This patent-at-issue today has a specific recitation of a very particular dose 0.25 milligrams in a 5 milliliter solution, whereas some of the previous claims referred to a concentration of palonosetron of 0.05 milligrams per milliliter, and we think that conveys a fairly limited amount of dosages and volumes, but this patent that we're talking about today is very specific 0.25 exactly, 5 milliliter solution.

THE COURT: Okay. Thank you.

MR. DITTMANN: During this examiner interview the examiner summarizes what was discussed, and, again, it is

prior art being discussed, Tang, and she says that Mr. Sullivan, who was the prosecuting attorney for plaintiffs in response to these prior art assertions being made he highlighted the limitations that were in the claims, including, so these are not all of them, but he is including "limitations of the claims relevant to this prior art," and one of them is "cancer chemotherapy-induced nausea and vomiting" amongst others. The examiner goes on and talks about Tang, describing a dose-ranging trial in PONV. PONV, as your Honor may recall, is post-operative nausea and vomiting, a related, but different form of emesis than CINV.

THE COURT: And it gets a higher dosage, I think, generally?

MR. DITTMANN: Generally the CINV gets the higher dosage than the PONV. The PONV is less. Yes.

THE COURT: I misread that.

MR. DITTMANN: And, so, here we have a situation in the prosecution of the patent-at-issue defendant said there's no evidence that we relied upon the CINV language. Well, here we are. The examiner stating this a summary of what was argued by the applicants relying upon chemotherapy-induced nausea and vomiting language to distinguish the prior art.

THE COURT: Okay. So, Tang had to do with this other use, which is post-op, post-operative, whereas this application that resulted in the '219 is for cancer

chemotherapy-induced emesis, right?

MR. DITTMANN: These PONV and CINV conditions are related, but, again, they're different. They're different, but they are related, and, again, I think your Honor was accurate that there's a dosage relation that one takes more dose than the other. But what we can't deny is that the applicants state very clearly when they identify the limitations in the claim the examiner expressly writes this language, which was based on arguments from Mr. Sullivan.

THE COURT: So, in other words he is trying to distinguish prior art in the form of this Tang patent that addresses PONV, whereas the current application is addressing CINV?

MR. DITTMANN: CINV. And, if I can give you a little context of what's happening here is this Tang reference discloses that you need at least 2 milligrams to have partial efficacy in PONV, and what we are arguing to the Patent Office is, well, look, if you need at least 2 milligrams for PONV and only get partial efficacy, there's no way 0.25 milligrams for CINV, which typically requires more dose could be obvious. So we're using Tang to suggest that 0.25 milligrams for CINV couldn't possibly be obvious based on the disclosure of Tang.

THE COURT: So, it is not just the wooden distinction between a patent directed at a PONV therapy and another patent directed at CINV. It is more than that. It is that the

dosage --

MR. DITTMANN: Yes.

THE COURT: -- comparison produced some surprises.

MR. DITTMANN: Yes. The Tang study we think was -- suppose it would have found the results of Helsinn's clinical study showing a very low-dose of palonosetron being effective for CINV to be very surprising in terms of what Tang taught in the prior art. Tang suggested you need a much higher dose.

THE COURT: Well, we will get there, but your adversaries say, so, good; why aren't the clinical -- or at least the lab results of this therapeutic effect then contained in the specification for the '219 patent? But I'm sure you'll get there.

MR. DITTMANN: Yes. To be clear, your Honor, that is the written description defense. It is not a claim construction dispute. But just to quickly preview that defendants have a fundamental misunderstanding of the law with respect to the written description defense that we'll make very clear to your Honor at the appropriate time, but I can tell you that no matter how you view the specification there cannot be any doubt that it provides written description support for what's claimed, the formulation that's claimed as being capable of treating CINV a person of skill in the art reading that specification wouldn't have any doubt. That is the case based on that disclosure, but we'll address that at

the appropriate time if it ever comes.

And, so, basically, I want to make sure that we're clear on --

THE COURT: Incidentally, while we're switching slides, we will take like a five-minute recess before your adversaries have to get up and speak just so everybody is not starting to get uneasy in the room.

MR. DITTMANN: It was going to slow me down, your Honor.

THE COURT: And you have all the time you need, both sides.

MR. DITTMANN: Thank you. The Vizio case we cited we think is instructive. It is an analogous situation where it is an apparatus claim, and it is talking about in the preamble this function or whatever you want to call it, intended use or function of providing decoded program data. And here the Federal Circuit found that this language requires that the apparatus must be actually capable of doing this decoding. And I want to be clear, defendants in their briefs have suggested that we're arguing that this CINV language means that the formulations have to be actually used in order to infringe. That's not what the claims require. That's not what we're saying. We're just saying it has to be capable of doing that. Whatever the formulation is, if we're going to allege infringement of that formulation, that formulation has

to be capable of being used to treat CINV in humans.

THE COURT: I dimly recall that you had the -- if you try to put the actual use of it into the patent then the users wind up being sued for patent infringement because they're practicing the patent, and, so, that's why the patent drafter stops short of saying, "and you use it."

MR. DITTMANN: Right.

THE COURT: So, they say it has to be capable of being used that way.

MR. DITTMANN: So to be clear, these are formulation claims that have this capability. You know, formulations, of course, can be used for many different things, different medical purposes. Here we're being very particular that it has to have the capability of treating CINV. And this is analogous, again, to this Vizio case where this capability-type language in the preamble because it was a fundamental characteristic of the invention, which we think is the case here based on the prosecution's statements alone, we think it is analogous, and, again, to briefly refer back to the specification we went through a number of disclosures showing, again, that this idea of reducing chemotherapy form of emesis is a fundamental characteristic of what this invention is all about. These are medicines for a particular purpose.

THE COURT: Now, palonosetron has other potential

uses, as well, such as the post-surgical, post-op application, right?

MR. DITTMANN: There's certainly that. Medicines can be used for a whole host of reasons. I know setrons were investigated in the 1990s for anxiety and depression. So, again, a formulation can be used for different purposes, and, again, the inquiry -- we're not saying that in every case, you know, the formulation claims have to have some sort of a capable use characteristic, but in this case under these facts -- forget about general principles; apply the facts, and under these facts the limitation is clearly serving to circumscribe the claim.

And that's all I had at least for now. I would like to save some time for rebuttal, and I appreciate your patience, your Honor.

THE COURT: Fine. Let's take our five-minute recess now. Thank you, Mr. Dittmann.

MR. DITTMANN: Thank you.

(Brief Recess.)

THE COURT: And Mr. Wong.

MR. WONG: Your Honor. May it please the Court. Good afternoon, Your Honor. It is good to see you again. My name is Jovial Wong from Winston and Strawn, and I am counsel for the Teva defendants. I'll also be making this argument on behalf of Sandoz and DRL.

Your Honor, this is just a preview of what I'll be addressing today, but, certainly, if you have any questions along the way feel free to ask them, and I'll answer them as they come up.

By now I think you know where the parties stand, so on the background issues I'll try to be brief. The preamble language that is disputed by the parties is not a limitation of a claimed palonosetron formulation. And the analysis in our view is really quite simple. As I will explain, the law of the Federal Circuit is that in general preamble terms are not limiting. And more specifically, for terms of intended use like we have here, preambles are not limiting. That is the starting point that we have here, and plaintiffs have an uphill battle to show otherwise.

Now, this general rule that preambles aren't limiting is not a blanket rule that applies to every preamble term, and, certainly, we're not arguing that. We agree that the rule is applied on a case-by-case basis, and that's what we have done here. And after considering all the evidence it is clear that plaintiffs's reliance on two exceptions don't meet the requirements that transforms the disputed preamble language into a limitation.

I just want to take a minute to set the proper context that we have here for the '219 patent. And, Your Honor, I think this will help you in your understanding of the disputed

preamble language. As counsel explained, this is Claim 1 from the '219 patent. It starts with the preamble, and it says, "a pharmaceutical single-use unit-dose formulation." The preamble then has the intended use, which is at issue here. "For intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting; i.e., CINV." We have highlighted this intended use, the disputed preamble language in red. It doesn't show up too well, but, certainly, in the slides I think it is more apparent.

Now, to take a step back, the '219 patent is all about palonosetron formulations. More specifically, as you recall, the alleged discovery was that the inventors came up with a way to make a palonosetron formulation more stable than what was already known in the prior art for intravenous palonosetron formulations. So, this is reflected here in Claim 1. As you see, the claim is a pharmaceutical single-use unit-dose formulation. It lists out several formulation specifics in the body, including a 5 milliliter solution, 0.25 milligrams of palonosetron and, also, various concentrations of excipients like EDTA and mannitol. And at the end the result of all of this is that the formulation is stable for 24 months when stored at room temperature. That is the essence or central aspect of the alleged invention of the '219 patent. Using it to treat emesis or CINV is not the central aspect,

and because the use of palonosetron as an antiemetic was already known in the prior art.

Your Honor, I hope all of this sounds familiar because this is exactly what we discussed the last time we were here for claim construction. As you recall from those Markman proceedings, the disputed issue was the plain and ordinary meaning of the term "pharmaceutically stable." As you can see here in Claim 1 of the '724 patent it recites a "pharmaceutically stable intravenous solution." And the parties, both plaintiffs and defendants, we went on and on in argument in our papers as to why this improved stability was so important to the formulation and why it was a core aspect of the invention, the core invention. Well, your Honor, here we have the two claims, the '219 patent and the '724 patent.

THE COURT: Not so fast.

MR. WONG: The core invention of the previous patents, such as the '724, the '725, and the '424 patents is the same as the core invention in the '219 patent. It is improved stability formulations. And this makes sense because all the patents at issue here, all four, they share the nearly identical specifications, nearly identical set of inventors, and they all claim priority back to the same provisional application.

THE COURT: But I see a tonicifying effective amount of mannitol in your Claim 1 of the '724 patent.

MR. WONG: Right. And in --

THE COURT: And in the preamble it says "intravenous."

MR. WONG: Right. Right. So, in general, they all relate to palonosetron formulations and solutions, and as counsel explained there are different iterations of what is claimed, but, again, it is all formulations that have improved stability over the prior art as the point there.

And if you compare the claims specifically, you're right, they are very similar. Claim 1 of the '219 patent goes to a formulation. Same with Claim 1 of the '724 patent; it's a solution, a formulation. They both list out formulation specifics like excipients, concentrations, and they all have a stability aspect to it. In the claims of the '219 patent it is expressly listed out that the formulation is stable at 24 months at room temperature, and in Claim 1 of the '724 patent they have the term "pharmaceutically stable."

Now, each --

THE COURT: But, you know, "pharmaceutically stable" was a claim limitation, even though it was in the preamble of that '724 Claim 1, right?

MR. WONG: Right. Right. And plaintiffs have alleged that we have been inconsistent in our preamble and treatment of preamble language. I have a slide on that to address it. Basically, terms of structure, terms that add

essential structure and modify the solution, such as "pharmaceutically stable," such as "intravenous" in the '724 patent, we readily agree that those are limitations on the claim because they provide structure to the claim.

Similarly, in the '219 patent you have "pharmaceutical single-use unit-dose formulation," and the parties don't dispute that that adds essential structure to the formulation that renders it a limitation.

Each claim also has a '724 patent, and in the '219 patent they also have an intended use in the preamble. We know what the intended use is for the '219 patent; that's what we're disputing. The '724 patent claims, along with those of the other patents, recite "for reducing emesis" or "reducing the likelihood of emesis." It is another intended use in the preamble, and we have been consistent the whole time through. We say it is that intended use is not limiting here, and it is also not limiting for the previous patents. We have always been consistent, and our experts have taken that same position.

And I'll explain why the fact that both claims have an intended use is important. But moving on, so, as you know, what we had before you is whether the intended use language of the preamble is a limitation of the '219 claims. We say that it is not per the general rule of the Federal Circuit. Plaintiffs say that it is, and they rely on only two

exceptions to that general rule.

And you asked this question, plaintiffs addressed it. But why does the disputed preamble language matter? Your Honor, you asked this question with regard to "pharmaceutically stable." We thought you might be wondering the same about this term after reading the briefs. The answer is the same as last time. Plaintiffs are taking the opportunity here at Markman to add in another limitation to try to save their claims from being invalidated. Before they took a narrow interpretation of the term "pharmaceutically stable," and they said it had to mean 24 months at room temperature, again, to save -- to protect their claims from an obviousness or anticipation attack.

Here they're trying to say that the intended use, which is disputed here, is another limitation of the claims, and, your Honor, it matters. If these terms are limiting, as plaintiffs contend, and we think that's contrary to the law, it adds another limitation that we as defendants have to deal with with respect to our defenses of obviousness and anticipation. And, you know, we have had our experts take alternate positions with the prior expert discovery session and now in this current expert discovery phase. And, so, they interpret the claims as invalid whether or not the preamble is a limitation waiting for further instruction from the Court.

So, plaintiffs's reference to --

THE COURT: Wait a minute. So, plaintiffs to say today they don't know why you think this Markman dispute has to be decided, you're saying it goes to our defenses of obviousness and anticipation?

MR. WONG: Correct. That's exactly right. And we're surprised that plaintiffs contend that they're confused about our positions. We have been clear the whole time. In all of our expert reports our experts have said the claims are invalid, even assuming that the limitation at issue, the intended uses, are limitations. They have taken both positions. It is not a limitation, it is a limitation, and in either case they said it is not obvious -- it is obvious or anticipated. We don't think that it is a limitation, and at trial we don't think we should have to address that limitation in our defenses.

But I was going to say plaintiffs flashed some excerpts from our expert reports, and to be honest, your Honor, those are taken out of context. Those are from portions of our expert reports where they did assume it's a limitation. So, that's why they had to address it in their experts's reports.

THE COURT: Or they did assume that it would be construed to be a limitation.

MR. WONG: Correct, because we want to cover our bases just in case the Court decides it in plaintiffs's favor.

So, now let's take a look at how the Federal Circuit

actually treats the preamble of a claim. Your Honor, generally the preamble does not limit the claim. That's right from the Federal Circuit's case in Allen Engineering. All the way since 2002 this has been the way the Federal Circuit deals with preambles. And specifically, the Federal Circuit has said, "a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim."

If a preamble term doesn't do any of this then it is not limiting per the Federal Circuit's general rule. And this is the general rule that the Federal Circuit has used since 2002 when it handed down its Catalina Marketing V Coolsavings case. Your Honor, that is a seminal case on preamble interpretation. It is cited by all the Federal Circuit cases since 2002, and what it is telling you, your Honor, is that plaintiffs's briefs never affirmatively rely on Catalina Marketing to support their position because it doesn't. And the logic behind the rule that preambles are not limiting makes sense. A preamble, as the name suggests, is just the introductory part of the claim, right? It provides a general gist of what the claimed invention is, whether it is a compound, a formulation, a process, a method.

In contrast, the body of the claim, which is what follows a preamble, is really where the Patent Office wants the inventor to define the metes and bounds of the invention

they claimed. Here the body of the claim has all the specific ingredients that make the palonosetron formulation stable.

So, how do you determine whether the preamble recites essential structure or gives meaning to the claim? The Federal Circuit says look at the body of the claim. Here again it is Claim 1. In Catalina Marketing at 809 the Federal Circuit says, "The preamble is generally not limiting when the claim body describes a structurally complete invention, such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Your Honor, that is exactly what we have here in Claim 1 of the '219 patent.

Again, the preamble starts with "a pharmaceutical single-use unit-dose formulation," and then it continues with the intended use. The body of the claim that follows lists all the formulation specifics. So, the body of the claim, plus these structural terms in the preamble "pharmaceutical single-use unit-dose formulation," which everyone agrees is limiting, together they define a structurally complete invention. "A stable palonosetron formulation that is a core invention." And we know it is structurally complete, your Honor, because look what happens when you remove the intended use. When you remove the disputed preamble language, which is shown in this next Slide 10, you end up with the same thing. "A stable palonosetron formulation that is a core invention."

Nothing changes. You still have everything you need to define a formulation that is stable at 24 months when stored at room temperature.

Your Honor, the point here is that the intended use that is in the preamble is unnecessary. It is not essential to the claims, and if that is the case, the Federal Circuit says it is not limiting.

THE COURT: What about the intravenous aspect?

MR. WONG: Right. Right. And I'll get to that.

THE COURT: I mean, I really see this as two phrases, I must say. "For intravenous administration to a human" is one phrase.

MR. WONG: Right.

THE COURT: And then "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" is a second phrase.

MR. WONG: Right.

THE COURT: I think that each of you are addressing your arguments to each phrase. You're not just lumping them together. Mr. Dittmann certainly did. So I'm trying to hear it that way.

MR. WONG: Right. And I will address both of these phrases of the disputed preamble individually, but our position is that both phrases, all of the disputed preamble language is not limiting, and I'll show you why.

So, here the point is that the claims without the intended use provides a structurally complete invention. That shows that the intended use is not necessary. And specifically with respect to intended uses terms, intended use terms in the preamble that we have here, the Federal Circuit is very clear that they are generally not limiting. This is from the Catalina Marketing case, again, and there the preamble term at issue was an intended use. The phrase -- and I'll show you later -- the phrase was "a system for controlling the selection and dispensing of product coupons..." and it goes on. So, it had a structure part, and it had an intended use.

And it is a very narrow limitation that the Federal Circuit has a very narrow exception that the Federal Circuit has allowed for intended use specifically. And in all of their briefing plaintiffs cite only two cases, and including our cases that we have cited there are only two cases that have been cited to the Court that have found intended uses limiting. That's the In Re: Stencil case and the GEV Nintendo case.

THE COURT: What was first one?

MR. WONG: In Re: Stencil. While the preambles, they were intended uses, and they were found limiting in those cases, there was a clear antecedent basis exception that made it limiting, and, Your Honor, as I'll explain, that just isn't

the case here. There is no such --

THE COURT: You're going too fast. I'm not getting it.

MR. WONG: Right. So...

THE COURT: I'm your audience.

MR. WONG: My point here is that intended uses are --

THE COURT: There was a clear and what?

MR. WONG: Antecedent basis exception. It was a clear exception in those two cases. That is not here. And, so, that is why our intended use position here is that it is not limiting because the same exception doesn't apply here to make it limiting.

THE COURT: And you just cited the two cases where you saw that uses or benefits in the preamble?

MR. WONG: Right. And those are the only two cases among all the cases on preamble limitations where intended uses -- or the issue of intended uses in preambles was up for determination whether or not it is limiting or not.

THE COURT: Would that be without resort to the prosecution history, those two cases?

MR. WONG: Exactly. I think including the prosecution history, all the cases for the most part say that intended uses are not limiting. These are the only two cases that say it was limiting, and there was a clear antecedent basis exception in both of those two cases.

So, in addition to looking to see whether the disputed preamble language adds essential structure, the inventors's own statements during the prosecution are dispositive on this issue, your Honor, despite what plaintiffs's counsel has suggested.

Plaintiffs rely heavily on the prosecution history of the '724 patent, '725 patent, the '424 patents in their briefing, and the Federal Circuit certainly allows this when interpreting the claims of the '219 patent. But, your Honor, they failed to address and take on what are the most important statements. And, again, before we get there I'll go back to the similarities between the claims. Both the claims of the '724 patent and the claims of the '219 patent have this intended use in the preamble.

THE COURT: Roughly.

MR. WONG: Roughly. And according to -- they're both intended uses; that's not disputed.

THE COURT: Right.

MR. WONG: And according to plaintiffs in their briefing they said these are virtually identical intended uses. That's right from both their opening brief and their reply brief. And, so, how did the inventors treat the intended use that was in the preambles of the '724 patent before? They admitted that the intended use was not, was not one of the limitations of the claimed palonosetron

formulations, and they did this multiple times for each of the claims of the '724, '725, and '424 patents that had the same intended use in the preamble. And, so, here's a prosecution history, all three of the patents went up to appeal at the Patent Office, and here is what is required by the Patent Office rules when you file your appeal brief. "Summary of claimed subject matter:" should include, has to include, "a concise explanation of the subject matter defined in each of the independent claims involved in the appeal."

Now, plaintiffs suggest that, well, the preamble was not at issue anymore by the time the cases got to appeal, but, your Honor, we think that's a red herring.

THE COURT: Involved in the appeal.

MR. WONG: Right. Because bottom line is that the Patent Office requires an explanation of what the claims are. That's the bottom line. That comes right from --

THE COURT: So, you would say any claim that's involved in the appeal, not just any claim term --

MR. WONG: Exactly. Exactly.

THE COURT: -- that's involved in the appeal.

MR. WONG: Here's the excerpt from the '724 patent appeal brief. And it is the same thing for each of the '725 and '424 patents. Summary of the -- the subject matter -- again, it is the entire claim, not just the limitations. It is entitled, "Summary of the claimed subject matter," which is

the entire claim, not just specific limitations that are involved in the appeal. And in this section the inventors describe Claim 32, which eventually became Claim 1 of the '724 patent, the inventor said that "the claimed subject matter was a formulation of palonosetron characterized by a combination of ingredients, ingredient concentrations, and physical characteristics." That's it. Those are all limitations in the body of the claim. And to be even more clear, they said, "The claimed formulation is limited by the following features:"

Your Honor, none of the features -- they go on to list one through six -- is the intended use for reducing emesis or the likelihood of emesis. So, each time they went up on appeal the inventors -- and it is the same inventors of the '219 patent -- they admitted that the intended use in the preamble of these claims are not limitations of the claims, are not features of the claims. For the same reason here, your Honor, the virtually identical intended use --

THE COURT: I still see the word "intravenous" there because it is right in the listing of the '724 ingredients.

MR. WONG: Exactly. So, the claims of the '724 patent and the '219 patents are worded differently, and it is not just semantics, which plaintiffs try to suggest. It is actually claim drafting, and it makes a difference. But the point here is that --

THE COURT: One never knows.

MR. WONG: The virtually identical intended uses of the disputed preamble language can't be a limitation because they weren't before. We think that's dispositive, and plaintiffs still haven't credibly shown why that shouldn't be the case.

So, to address your point that these claims of the '724 patent embodied in an intravenous solution, that's absolutely correct. That's right there in Claim 1 and point one, and that's what the inventors rightfully said to the Patent Office. But going back just two slides to compare it, that has no bearing on the '219 patent claims, Your Honor. And in the '724 patent the inventors affirmatively claimed an intravenous solution, right? Intravenous was not part of the intended use for reducing emesis or reducing the likelihood of emesis.

THE COURT: What?

MR. WONG: If you see in Claim 1 it says, "a pharmaceutically stable intravenous solution" and then the intended use "for reducing emesis or reducing the likelihood of emesis." So, they affirmatively claimed that their solution there in Claim 1 of the '724 patent was an intravenous solution. Here if you look at Claim 1 of the '219 patent, it is different. It claims "a pharmaceutical single-use unit-dose formulation for intravenous

administration," but "for intravenous administration" is not affirmatively claimed; it is part of the intended use. And, Your Honor, it makes a difference because the Federal Circuit treats structural claims -- structural terms differently than intended uses, as I reviewed.

THE COURT: I honestly don't think that the word "for intravenous administration" is distinguishable from "intravenous solution." It adds nothing. I mean, in that one respect I probably don't see a distinction. If it is an intravenous solution it connotes that you have to have a certain structure parameter, but it also connotes that it is going to go in a vein. So, maybe it is both.

MR. WONG: We don't dispute that, but for technical patent claim drafting it does make a difference because it is part of the intended use. Now, they could have drafted the '219 claims to say "an intravenous formulation," and if they did that, we wouldn't argue that that provides a central structure to the formulation and that would be limiting, but, your Honor, respectfully, our position here is that because "for administration" is part of the intended use, the Federal Circuit case law treats that differently and treats that not as a limitation.

THE COURT: You mean the minute you have got the preposition F-O-R everything after it is wiped out, unless an exception applies?

MR. WONG: That's our position.

THE COURT: Wipes it out from being a limitation?

MR. WONG: Right.

THE COURT: That sounds awfully literal to me, but go ahead.

MR. WONG: Right. And it is a literal interpretation, your Honor, but under the law that's how these claims should be interpreted.

Now, so just wrapping up on the Federal Circuit law, the fact that the claimed formulation without the intended use is structurally complete, and, number two, the fact that the inventors pretty much admitted this to the Patent Office we think that that shows that the preamble language that's in dispute is not limiting. It is consistent with the Federal Circuit law, the general rule that these kind of intended use terms are not limiting.

THE COURT: How about the fact that there was actually an amendment to the part of the preamble '219 language that took out the word "prevent" this CINV and replaced it with "to reduce the likelihood." That featured in the prosecution history of this '219 patent, right?

MR. WONG: That was made in the prosecution history not of the '219 patent, but of the parent patents, and we have slides on that. We'll address that. Your Honor, under Catalina Marketing, which requires that the term be

distinguished from the prior art, not just to overcome a 112 rejection, we think that is not enough under the current controlling case law to apply.

But just to kind of address your point on the two parts of the disputed preamble language, one part is "for intravenous administration," the other part is "to reduce the likelihood of CINV." Again, our position is that both parts of the disputed preamble are not limiting, but, certainly, if your Honor thinks that plaintiffs have shown enough evidence to say that the "for administration" part is limiting their evidence on the latter part "for reducing CINV," certainly, we think that is not limiting, and I'll show you why that is the case.

THE COURT: I'll follow you.

MR. WONG: So with respect to the two exceptions, and, again, the burden is on plaintiffs to show that these two exceptions apply, neither of them apply in our case. That's because the exceptions are very limited according to the Federal Circuit, and they require specific and unmistakable reliance to show that the intended uses are limiting. Your Honor, we think it is a high burden and plaintiffs's evidence is insufficient.

First --

THE COURT: I wonder what the reason is behind that general rule, but I'll have to study Catalina Marketing.

Go ahead.

MR. WONG: Actually, Catalina Marketing does make some comments -- the Federal Circuit does explain why in general preamble phrases that have intended uses aren't limiting, and I have a slide on that. I'll get to that later. It is because patentability in general is based on the structure of the claims, not the intended use. That's why intended use is especially for composition claims like we have here are not limiting.

THE COURT: Okay.

MR. WONG: So, first, the antecedent basis exception. From Catalina Marketing this exception requires reliance on both a preamble and the claim body to the defined invention. And here is a simple example of how this exception is applied in all the Federal Circuit cases. So, take -- this is going to be a hypothetical -- take the claim of a car for driving on a highway, the car comprising A, B, and C. Okay. "A car for driving on a highway." That's the preamble. Okay. "For driving on a highway" is the intended use of the claimed car, and that is generally not limiting; it is not a limitation of the claims. It will be a limitation of the claims if there is something else in the body of the claims, such as, "wherein the highway is 20 miles long." That kind of statement, that statement in the body, thus, makes the reference of "a highway" in the preamble a limitation because that shows that

the inventors used both the preamble and the claim body to define their invention. That's how it works. That's the kind of clear antecedent basis that all the Federal Circuit cases require. And, Your Honor, that just isn't met here, and I'll show you why for Claim 1.

So, here's Claim 1...

THE COURT: For driving on a highway at speeds between 50 and 75 miles an hour. Where do you break it up?

MR. WONG: Unless there's something in the body of the claim that references a term in the preamble, the case law is clear that it is not limiting. Okay.

So, in my example --

THE COURT: None of it?

MR. WONG: -- the highway was 20 miles long, that makes the highway a limitation of the claims.

THE COURT: Okay.

MR. WONG: So let's apply that analysis to Claim 1 of the '219 patent. And I'm going to step through the disputed preamble language step-by-step to show why this is not the case.

So, the first part of the intended use is "for intravenous administration." Okay? Your Honor, if you look down to the rest of the claim, there is no reference to said "intravenous administration" or anything like it.

THE COURT: That's true.

MR. WONG: That's just absolutely not there. In other words, "for intravenous administration" does not provide antecedent basis for anything in the claim.

I'm going to keep going.

The next part of the disputed preamble language is "to a human." Again, there's no reference, there's nothing in the rest of the claim "to a human." And, finally, "to reduce the likelihood of CINV." There's nothing in the rest of the claim that references CINV, reduction of the likelihood, nothing like that. And that's what the antecedent basis exception requires. And it is not surprising because the body of the claim are all stability terms. They're all what is required to make the palonosetron formulation stable.

THE COURT: Well, there's also a therapeutic dosage.

MR. WONG: Right. That's just the amount of palonosetron in the formulation. And, your Honor, with respect to the specification they said that low concentrations, low doses of palonosetron was important to make it stable because it is all about stability. It certainly doesn't say 0.25 milligrams to reduce the likelihood of CINV. And, in fact, as you read the specification, there's nothing in the specification regarding clinical trials or showing that 0.25 milligrams is the effective dose for CINV.

THE COURT: Well, they assert it in the specification. They say, surprisingly, we found that these

low doses are still effective for this therapeutic purpose.

MR. WONG: Right.

THE COURT: But then there's no lab tests.

MR. WONG: It is unsupported, your Honor. And more specifically, it was already known in the prior art that palonosetron was an effective antiemetic, so although they say that one statement, the rest of the specification is all about stability, they supplied no data to show that they actually discovered that, and that is the basis of our written description requirement -- our defense for written description for these claims. Because there was no disclosure in the specification to support that -- to support this intended use, to be frank.

THE COURT: So, even if you had this intended use as a claim limitation you would still have your written description defenses, which you have said?

MR. WONG: Exactly. Specifically because it is a limitation, we think there's no support. If you find that it is a limitation we think there's no support on it. That's an additional defense that we'll have at trial.

So, again, because there's no antecedent basis provided by anything in the disputed preamble language we think that the intended use language is not a limitation of the claims.

Now, plaintiffs make the argument that we parsed the preamble arbitrarily and without rational basis, and some

cases agree that preamble terms are limiting and other cases are saying that they are not limiting.

Your Honor, this is not the case at all. Our reading of the preamble is grounded in a rational basis, grounded in Federal Circuit precedence. The preamble can be divided as follows: You first have the structural terms, which is -- that's in green. "A pharmaceutical single-use, unit-dose formulation." We know the formulation is a limitation because it provides direct antecedent basis for "said formulation" later in the claims. There's no dispute there.

The terms "pharmaceutical single-use unit-dose" are structural terms that add essential structures to what the formulation is.

THE COURT: Well, your adversary points out "single-use."

MR. WONG: Right.

THE COURT: Says you're only going to use it once.

MR. WONG: Right. And, Your Honor, to address that point, this is the first time we have been hearing about this in their briefs for plaintiffs to come up with a reason why it involves a use. The fact of the matter is --

THE COURT: The word "use" is right there.

MR. WONG: The fact of the matter is "pharmaceutical single-use unit-dose" doesn't relate to how it is used. It relates to the formulation -- how the formulation is packaged

and supplied. Our experts put in expert reports on this limitation giving that exact same definition. Their experts came back with expert reports that didn't even address it. Didn't even dispute it. So, the definition that "single-use unit-dose formulation" adds use is wrong. Our experts have said it is the packaging -- it is how the formulation is packaged and supplied. That's unrebutted in expert discovery.

THE COURT: Who are you going to dose this unit to?

MR. WONG: You certainly give --

THE COURT: A human.

MR. WONG: Right. You certainly give it to patients.

THE COURT: Not a cat.

MR. WONG: That's right. For all intents and purposes the specification is about giving it to humans. But the fact is the claims don't require that. The claims say only in the intended use. There's no "human" limitation in the claims. The "pharmaceutical single-use unit-dose" portion is structural. It is not use. And their experts have not contested that.

THE COURT: You know, it is odd. You seek to erase this language, and then having erased it, you're going to attack the patent as not being specific enough. I don't get it.

But go ahead.

MR. WONG: We're only attacking the patent because it

is not specific enough if this is -- if the intended use is a claim limitation.

THE COURT: Precisely. It is a catch-22. Judge, erase it, and then once it is erased it is not there, so the patent isn't sufficiently specific on these points.

MR. WONG: Right. That's one reason why we say it shouldn't be a limitation because it is not supported.

THE COURT: Well, that's a different argument. Right now you're using a technical one, which is if it says "for" then it is out. Read it out, unless some exception applies.

MR. WONG: Exactly. That's what our position is.

THE COURT: Okay.

MR. WONG: And plaintiffs have alleged that we have been inconsistent in our way of treating preamble limitations. They have referred to our agreeing that limitations "pharmaceutically stable," "intravenous," "isotonic" in the '724 patent claims are limitations, and here we say that -- we definitely agree they're limitations because they provide essential structure. They were affirmatively claimed. Here all we're saying is that the intended use does not provide essential structure, as I have shown. It is a structurally complete intention even without the intended use. And even if that is what the formulation that is claimed is used for the Federal Circuit says that is not enough to make it a limitation. This is from the Marrin case that we cited in our

brief.

THE COURT: So, if it modifies a noun, if it modifies a subject in the sentence then it is structural. But if it modifies --

MR. WONG: It is actually just being capable of performing that function. It is an intended use. It doesn't directly modify formulation, which is our point.

THE COURT: "Administration" is a functional word, and "to reduce" is the form of a verb, whereas "formulation" is just a subject noun. If you're saying that grammar rules here I'm going to be surprised, but that's, basically, what you're saying.

Go ahead.

MR. WONG: According to the Federal Circuit that's how you treat intended uses when they are in the preamble.

Here the Federal Circuit said the same thing. "The mere fact that a structural term in the preamble," for example, "formulation," the subject, the noun, "is part of the claim does not mean that the preamble's statement of purpose; i.e., the intended use or other description is also part of the claim." So, structural terms like "formulation," "a pharmaceutical single-use unit-dose formulation," which we agree is the claim, the Federal Circuit says that's fine, but for intended uses those are limitations.

At the end of the day the Federal Circuit treats

structural terms differently from intended uses.

THE COURT: Does it matter what kind of a patent it is? I mean, we have what we call "product patents" and then we have "method patents." Some other kinds of patents.

MR. WONG: Right. And it does matter. Here we have product patents, composition claims, intended uses aren't limiting. For methods of using it, certainly, they can be limiting.

Another argument in here is the argument that you brought up is a difference between "for intravenous administration" and it is providing antecedent basis for the term "isotonic." And here we have "for intravenous administration" in the preamble and "isotonic" in the body of the claim.

Respectfully, your Honor, this is just not how the antecedent basis exception works under Federal Circuit cases. This is an apples-to-oranges comparison. You need something specific. You need a reference to said "intravenous administration." You need the term like "the isotonic solution" in the preamble in order for it to match up. That doesn't do it here, nor does "isotonic" need clarification, as the plaintiffs suggested in their briefs. The parties agreed -- we agreed during the last round that "isotonic" has a plain stand-alone meaning. That's not disputed. And during discovery experts have not disputed the meaning of "isotonic."

THE COURT: Which means it is associated inexorably with an intravenous use.

MR. WONG: That might be how the specification in its full disclosure describes different kinds of formulations, but, your Honor, in the claims the only limitation that you need is that it be isotonic. It doesn't need to be an intravenous solution literally under the claims. And it is for intravenous administration, but it is not an intravenous formulation when looking at the claims. And you might subsume the same thing with the term "isotonic," but with regard to the question does it have to be intravenous, under the claims of the '219 patent, it doesn't have to be.

The American Medical Systems case cited by the Federal Circuit says the same thing. "No antecedent basis where the preamble term did not provide context essential to understanding the meaning of the term in the body of the claim." "Isotonic" or "for intravenous administration" does not provide essential context for "isotonic" because none is needed. "Isotonic" is a stand-alone term that is well understood.

So, again, for the antecedent basis exception all the plaintiffs's evidence we think is insufficient to transform the disputed preamble language into a limitation, including both parts, the "for administration" part, as well as the "CINV" part. And as your Honor acknowledged, while "for

intravenous" -- if you decide that "for intravenous administration" is limiting we, of course, disagree, but as far as the antecedent basis exception plaintiffs have not brought forth any evidence to show that the reducing the likelihood of CINV has antecedent basis for anything in the claims. That shouldn't be a limitation.

THE COURT: I follow your argument. I just follow in the sense that you can understand that there might be distinctions between these phrases that could be made, which you don't agree with. Right?

MR. WONG: Your Honor, the second exception is the prosecution history exception.

THE COURT: Right.

MR. WONG: We think that their evidence doesn't meet the requirements, and this is the requirement, again, from Catalina Marketing. The Federal Circuit required two things. Clear reliance on a preamble during prosecution and specifically to distinguish the claimed invention from the prior art. That's clear. Plaintiffs --

THE COURT: So, not just that you had to give up something during prosecution history in order to get your patent, it is not like prosecution estoppel.

MR. WONG: Precisely. It matters whether it is to distinguish prior art or whether it is just to overcome a rejection like a 112 rejection. Under Catalina Marketing,

which we think is controlling, you need to distinguish prior art. That was never done for any reference in the prosecution history for any patent.

So, let's start with what was discussed in the '219 patent, okay? As plaintiffs's counsel suggested, it was very brief. Only two references were raised by the examiner. The CDER reference and the Baroni reference. But neither reference was distinguished from the claimed invention and certainly not by relying on the CINV part or any part of the disputed preamble language. Instead, the inventors overcame the art based on a technicality. They said that it came too late in time, and it was published only after the filing date, and that is what is shown here in the prosecution history. The CDER publication does not qualify as prior art. It made the same representation with regard to the Baroni publication.

Now, plaintiffs in their argument they raise the examiner -- the interview summary with the examiner. And they suggest that statements made by patent counsel, Mr. Sullivan, suggest that the CINV part of the '219 claims is a limitation. But, again, your Honor, closer examination of the prosecution history shows that's not the case. Here's the entire examiner interview. I think plaintiffs just showed you the top portion. And in the entire interview they talk about three topics, okay? Plaintiffs just discuss the first topic.

So, first the examiner discussed the claims themselves,

not the prior art, and found it strange that there was no pH limitation in the current claims because there was a pH limitation in the preceding claims. And you see that right here in the beginning. "The examiner discussed with Mr. Sullivan the lack of a pH limitation in the claims." Okay? In response Mr. Sullivan highlighted, and, actually, made kind of a self-serving statement to say here are the limitations, including CINV at the bottom.

THE COURT: I don't understand what the lack of pH limitation would present as a problem, but go ahead.

MR. WONG: I actually don't either. It is a very sparse interview summary. We certainly don't think it meets the clear and unmistakable reliance that is necessary.

But what is telling is Mr. Sullivan's arguments were not to distinguish the prior art, and even if it was, it wasn't -- there was no clear and unmistakable reliance on the CINV part specifically to distinguish the claimed invention. That is what the Federal Circuit requires, and that is just blatantly absent here.

Moreover, in the second and third topics that were discussed that is where Mr. Sullivan distinguishes the claims over the prior art, like Tang and the Berger reference. And in each case Mr. Sullivan, as you see here, he doesn't rely on the intended use of treating CINV as a point of distinction. Instead, he distinguishes the prior art based on the

formulation ingredients and concentrations like inventors have done throughout the prosecution history.

THE COURT: Well, I mean in the middle of it here is the applicant's attorney pointing out that Tang's data indicated that only a pretty high-dose of this active ingredient palonosetron significantly decreased the incidence of vomiting, and the requirement for rescue antiemetics, and, so, they're talking about comparing the necessary dosage for that use in comparing the current pending application and the Tang reference.

MR. WONG: Correct. And that's because there was, as you know from the body of the claim, there's a specific dosage requirement of 0.25 milligrams, and the discussion there is just to say that they are different; the claims are different in that respect. It doesn't say that the intended use for treating CINV is a point that is different from the prior art.

THE COURT: Well, they're talking, though, about how the 0.25 milligram dose described in these claims is much lower -- in other words, Tang's dose to get some results is much higher. They are talking about the use of this claimed drug, aren't they?

MR. WONG: We think they're talking about the dose because it is a specific limitation of what makes -- of what the formulation is. They are not talking about using it -- the differences between using it to treat CINV or PONV. And

the Federal Circuit, respectfully, your Honor, they require clear reliance, clear and unmistakable reliance on the prosecution history to distinguish the claimed invention. We just don't think that is here.

THE COURT: What if your preamble that you were attacking has the capability of being antiemetic, rather than being specific to CINV?

MR. WONG: We still think that is not -- that would not be supported here. Your Honor, what would be supportive, just to put out a hypothetical, is if Mr. Sullivan said our claims go to treating -- using palonosetron formulations to treat CINV or to treat antiemetics. The prior art is not used for this use. That would be a clear and unmistakable reliance on the prior art to distinguish their invention.

THE COURT: I don't necessarily agree. I'm trying to make sense out of this, and I don't have a preconceived notion about where I'm going, so this is a dialogue.

MR. WONG: Sure.

THE COURT: But they're not just talking about dosages in the abstract. They are talking about antiemetic usage and how the prior art, while it is an antiemetic, and so is this claimed invention, they're distinguishable, the prior art is distinguishable because of the significant difference in dosage. You know, maybe they're all wrong about the prior art, but that's what they're focusing on, and that discussion

is, okay, you have got the prior art that uses all this huge amount of stuff to get some antiemetic effect, and here is our new claim that just claims a very minuscule amount of the active ingredient, and we're getting -- we're talking about antiemetic use.

MR. WONG: Right. I think what you said as far as our claims claiming a minuscule amount a specific 0.25 dose that is what Mr. Sullivan used to distinguish the claims.

Now the context might be in the sense of CINV or at least Tang was talking about PONV and the claims are in CINV, but that really wasn't the critical reliance that Mr. Sullivan was relying on. He just said our dose is 0.25. The dose in Tang is higher. And that is a distinction that they relied on to overcome the prior art. It wasn't the fact that Tang talked about PONV or -- and the present claims talk about CINV as far as intended uses.

THE COURT: No, but I asked you the question: Well, what if our claim language at issue said "antiemetic" rather than "CINV," and you said your argument would be the same, that it is not enough of a clear prosecution history indication that the use -- that is in the preamble of the disputed claim language is limiting, but I see this word "antiemetics" right here in their discussion. So, it seems to me they're not discussing dosage in a vacuum; they're discussing dosage as it relates to being an antiemetic agent.

MR. WONG: And, again, I think that is a context certainly because that is -- you know that is what dosages apply to, but the specific dosage that they claim in the pending claims at the time of the '219 patent was 0.25 milligrams. They used that limitation to distinguish the prior art. And, again, that is not one of the disputed preamble terms, and that's why we're saying it is not relevant. It doesn't meet what the Federal Circuit requires as a clear and unmistakable reliance on the disputed preamble language because that's not one of the terms.

THE COURT: Well, we also agree, don't we, that claim limitations don't all have to be novel. You know, claim limitations can have lots that's in the prior art just so long as the patent examiner finds that the invention as a whole is novel.

MR. WONG: Right. Certainly.

THE COURT: Okay. Go ahead with your argument.

MR. WONG: Okay. So, instead of relying on clear statements in the prosecution history plaintiffs's reliance on the prosecution history really amounts to an apples-to-oranges comparison. Again, it is the difference between "intravenous" and "for intravenous administration." I won't belabor this point, but, your Honor, we think that none of the cases that plaintiffs cite allow the narrow prosecution history exception to apply one as an apples-to-oranges comparison of the claim

terms. Here the claim is "intravenous" in the previous prosecution, and the claim that we have here, the claim term here is "for intravenous administration."

THE COURT: Okay. Magic word being "for."

MR. WONG: Exactly. And the next slide I think is instructive because it really clarifies what was going on at the time they made the amendment to introduce "intravenous" into the solution.

Plaintiffs are correct that they amended Claim 32 -- again, that's Claim 1 of the '724 patent -- to narrow it to say "intravenous solutions," and they made the argument to the Patent Office that that distinguishes the formulation from oral formulations that were in the prior art. Again, that's "intravenous," it is not "for intravenous administration." But in the same amendment look at what they did to Claim 40. Claim 40 had adapted "for intravenous administration," and they deleted it. They couldn't argue that this limitation was sufficient to overcome the prior art for oral formulations. We think that's significant. They never used "for intravenous administration" to distinguish the prior art. They couldn't. They had to delete it and replace it with something affirmative, like "intravenous solution."

For this reason, your Honor, this doesn't meet the clear and unmistakable reliance that is required for the prosecution history exception.

Now, you brought this up earlier, your Honor. Plaintiffs rely on the fact that "preventing" was deleted from the preamble in the prosecution for the previous patents, such as the '724 patent. Your Honor, we think that this is not enough either.

First, it is important to put this in the right context, Your Honor. Claims with absolute terms like "preventing" or "curing" are routinely, as a matter of course, rejected by the Patent Office, and they're rejected under Section 112 because even with the best clinical data it is virtually impossible to show that something works 100 percent of the time in 100 percent of the people. The Patent Office is more amenable to phrases like "reducing" or "treating," which is why they replaced "preventing" with "reducing the likelihood of emesis."

So, the fact that the examiner made the plaintiffs remove "preventing" in the preamble doesn't demonstrate at all that this is a limitation. In fact, there was no argument either way by the examiner or the applicant that this preamble language was limiting. It was really only --

THE COURT: They would never talk about that, though, unfortunately.

MR. WONG: Well, if there really was an issue of whether or not the preamble is limiting, you would expect they would have raised it. They didn't raise it at all. It was

actually a form rejection; it comes down to being basically a form rejection that the examiner made, and they would make in any claim that had the word "prevent" in it.

THE COURT: Well, this distinction between whether preamble language is or is not limiting, I don't think it is something that the patent examiner or even the Patent Board of Appeals gets into.

MR. WONG: I think --

THE COURT: I think it is case law borne, right?

MR. WONG: I think that is correct, Your Honor. I think when we read the prosecution history there is certainly nothing that says it is a limitation, and that's what the prosecution history exception requires. Affirmative reliance on the preamble during prosecution to show that it is limiting, that's not the case here. Whether or not the Patent Office generally treats it as limiting or not limiting we say we think they generally treat it as non-limiting. It is just not clear from prosecution history. There's no evidence that anyone in the Patent Office treated it as limiting.

THE COURT: Is there anything in that handbook, you know, the patent Examiner's Handbook that talks about preambles and whether language in there is limiting or not?

MR. WONG: You know, I'm not sure.

THE COURT: This is just idle curiosity. You don't have to answer.

MR. WONG: I'm not sure. We didn't cite it in our briefs. Plaintiffs didn't cite anything to the contrary.

Second, your Honor, to put this amendment in perspective, the enablement rejection and the deletion of "preventing" was made very early on in the prosecution history. It was actually made in the first office action that the examiner issued, and there they objected to the word "preventing." That is in 2006, which, again, really shows it's a form rejection that the examiner made.

THE COURT: And it is Section 112, as you say?

MR. WONG: That's right.

THE COURT: It is not an obviousness rejection?

MR. WONG: Correct.

THE COURT: It has nothing to do with distinguishing the prior art?

MR. WONG: Precisely. After this initial rejection there was three years of substantive prosecution back and forth between the examiner and the inventors as to why the claim should be patentable. All of that discussion, your Honor, had to do with prior art that dealt with formulation specifics, whether it is the EDTA, the mannitol, the palonosetron concentrations. None of it had to do with the preamble language. And at the end, your Honor, in 2010 -- we already talked about this -- the inventors submitted their appeal briefs, and they actually admitted that the preamble is

not part -- was not part of the concise statement that they needed to make when they described their claims.

Again, the last thing, your Honor --

THE COURT: Where is that?

MR. WONG: It is on the chart. It is that last point, May 2010 when they submitted their appeal brief.

THE COURT: And what are they admitting there?

MR. WONG: When they were required to list out what their claim features are, they listed out features one through six. None of it included the intended use "for reducing emesis."

THE COURT: That's where you started your argument.

MR. WONG: Exactly. Exactly.

So considering that timeline as a whole really, your Honor, the fact that there was a preventing amendment early on in the prosecution it doesn't amount to the clear reliance, the unmistakable reliance on the prosecution history to make the intended use limited. So, and that's what is required by Catalina Marketing and all the rest of the cases that cite that.

So, how do the plaintiffs side step the requirements of Catalina Marketing? They rely on a single case Fantasy Sports that plaintiffs's counsel discussed, but that is irrelevant and distinguishable for many reasons. First, if not most important, Fantasy Sports was issued by the Federal Circuit in

April of 2002. Catalina Marketing issued in May 2002, and all the cases since Catalina Marketing require for the prosecution history exception that there is a clear reliance on the preamble to distinguish the prior art. Not just overcoming a 112 rejection. That's our position there.

Second, even if Fantasy Sports was applicable, which we don't think it is, plaintiffs's entire argument relies on a single footnote, Footnote Number 3, which really is almost passing dicta, and according to the footnote it says -- it talks about the preamble, but focuses on the "computer" limitation, and at the end of the day it is the "computer" limitation that they found was a limiting part of the preamble because it provided structure. It said nothing about the intended use of "playing football based on actual football games. "

This is what the original claim was in Fantasy Sports: "An apparatus for playing football based on actual football games..." The examiner put forth a 112 rejection saying there's no support, there's no disclosure for apparatus, it is too vague. So what they did -- and they overcame the 112 rejection -- is they replaced "apparatus" with "computer." They didn't touch the intended use, and they made no argument to say that it was limiting.

So, your Honor, if anything, if it is even applicable, Fantasy Sports is also distinguishable from our situation

because it doesn't stand for the proposition at all that the intended use part of a preamble can be limiting.

At the end of the day applying what we think is the appropriate controlling case law, it is clear that the prosecution history exception does not apply.

Your Honor, just a couple final points to wrap up here.

Plaintiffs in the briefing suggested that our position under the disputed preamble language is nonsensical. We obviously disagree. The hypothetical example they posited is a palonosetron formulation that had all the ingredients that are in the body claims, all the formulation specifics, but didn't have the intended use. It didn't have the ability to treat CINV. Plaintiffs said that such a formulation would, nonetheless, be covered by the claims under our reading of the preamble language, and plaintiffs pointed out that that was nonsensical. But, your Honor, far from being nonsensical, that is exactly what patent law requires.

Again, there is no dispute that all the claims here in the '219 patent they are all composition claims, a formulation of palonosetron. And as composition claims Catalina Marketing says, "...preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure not on the use or purpose of that structure." They go on to say, "this means that a patent grants the right to

exclude others from making...selling...the claimed apparatus or composition for any use of that apparatus or composition."

THE COURT: So, you're saying that this is really in there to benefit actually the patent holder, rather than to penalize the patent holder, the idea that if you claim a composition whether somebody uses it to fry an egg --

MR. WONG: Exactly.

THE COURT: -- or to go to the moon, the composition is infringed.

MR. WONG: Exactly. And in our briefing we made the argument saying that if our palonosetron formulations were used for treating, I think it is arthritis or Alzheimer's, they could still literally infringe the claims because all the formulation specifics in the body of the claims were met, even though the intended use was not met because it is not treating CINV, it is treating something else like Alzheimer's, and that's what the Federal Circuit has said. The bottom line is that intended uses for composition claims don't really matter. For method claims, yes.

THE COURT: I have seen, you know, a method of treating a, you know, human for diptheria and that now we found out that it can also be used for some other use and then you get a different patent for that.

MR. WONG: Right. Right.

THE COURT: Because it is a method patent.

MR. WONG: So for method claims the intended uses that are recited in the preamble those are limiting on the claims generally. Those are limiting on the method claims.

THE COURT: Oh, in method claims. Oh. Even if it is just in the preamble?

MR. WONG: It is because it is essential to what the method is. It is a general gist of what the method is, and it provides essential structure or I think another thing they said is that it provides essential steps, so it is a method for treating something specifically. We're not dealing with method claims here, we're dealing with composition claims. We think the Federal Circuit intended uses for composition claims aren't limitations based on what they say in Catalina Marketing.

So, let's see how the Federal Circuit applied this to Catalina Marketing claim specifically, and they're very analogous to the '219 patent claims. The preamble has both a structure and an intended use. Here in Catalina Marketing the structure is "A system." It is here in green. The intended use is "for controlling the selection and dispensing of the product coupons..." and it goes on. But the Federal Circuit found this use not limiting, and here's the rationale in the last quote. "In this case the disputed preamble language does not limit Claim 1 - an apparatus claim. To hold otherwise would effectively impose a method limitation on an apparatus

claim without justification."

Your Honor, this is precisely what plaintiffs are asking you to do. Impose a method limitation on a formulation claim without justification. We think that's improper under clear Federal Circuit precedence, therefore, defendants respectfully ask this Court to find that disputed preamble language is not limiting in the claims of the '219 patent.

Thank you.

THE COURT: Okay. Thank you. If there's anything that you absolutely must respond to I will let you briefly.

MR. DITTMANN: Thank you, Your Honor. I appreciate it. If you can just bring up that slide that you just used that would be great.

Just to make very clear, your Honor, this may be part of the defendant's misconception about this written description issue. We are not imposing a method limitation on these claims. Like the Vizio case, which is an example of intended use-type limitations requiring a capability of structure to be capable of doing something that's what we're saying, capable of treating CINV. We're not saying you have to impose a method limitation, actually treat a patient for CINV to satisfy the claims. That's not our argument. It has to do with a capability of the accused structure. Whatever the ingredients are in that accused structure is it capable of treating CINV.

More importantly, just briefly, I think that it seems like we're pretty much mostly there on the I.V. language, as your Honor correctly noted. We're really talking about rules of grammar and magic words at this point. He made no attempt to distinguish the meaning of these two phrases, which is really what matters.

Moreover, the prosecution of the parent applications that we went through, again, these terms, even if there was some possible basis to say they're slightly different, which we don't think there are, you still can rely on the parent prosecution to find this limitation to apply.

And there was no response, your Honor, and I'll get to the claim in a moment, you remember I showed you the body of the claim has the word "isotonic." That's clearly a claim limitation, and I showed you the prosecution history of the parent application where it said when you talked about isotonic in these claims it requires an intravenous formulation. So, putting this preamble dispute aside about grammar "for intravenous administration," if you look purely at the word "isotonic" and you look at the prosecution statements applying to that exact term an intravenous formulation is required by these claims irrespective of the preamble issue.

THE COURT: I think he said that nobody is going to dispute that this composition that's claimed is intended to be

an intravenous composition because of the word "isotonic" in the precise enumerated listing of ingredients.

MR. DITTMANN: Right.

THE COURT: He said what we're objecting to is adding the word "intravenous" as a limitation from the preamble because it is not in the right phraseology because it is phrased as a use there.

MR. DITTMANN: If defendants are willing to stipulate that "intravenous formulation" comes in through the word "isotonic" we're fine with that. There's no need for to us belabor this dispute on preamble, so we're certainly fine with that.

THE COURT: Now, if it were to be intracellular or intramuscular would "isotonic" introduce an ambiguity? You know, it might. We don't know sitting here.

MR. DITTMANN: I don't believe it would for purposes of this case, your Honor, but, again, the prosecution history answers that for us because it says when you use the word "isotonic" we're talking about intravenous formulations. It is clear. It takes that exact same language and says this is what we mean, and you take the patentees at their word when they make these sort of statements.

But I want to go back to this claim because, again, I think one big fundamental understanding is there's an argument about, well, unless the reference in the body of the claim

matches to what's in the preamble it doesn't limit. Well, defendants say that "single-use unit-dose" is a limitation of this claim.

THE COURT: Is a limitation because it is structural.

MR. DITTMANN: I'm going to get to that in a minute. But, first of all, I don't see that anywhere in this claim. So their matching tests clearly can't be right. It says, "said formulation." It doesn't say anything about single-use. Doesn't say anything about unit-dose. It simply refers back to "said formulation," which, again, the only context for that is in the preamble. So we'll start from that premise.

But I do want to address, your Honor, the single-use unit-dose argument, and I can provide you with these slides. These are a couple slides I had just in case these issues came up and you wanted to hear about them. But, again, going to these statements about general principles that it is a rare case that an intended use could limit a claim. Well, I want to explain why this is such a case and defendants have admitted that.

Again, the single-use unit-dose everyone agrees is a limitation of the claims. This is an expert report from Dr. Spilker, one of defendant's experts, who submitted this just last month. So this is a report addressing this point we're talking about today. And he says, single-use is if it is only used once and then discarded. Use. He says, unit-dose means

it has the amount of pharmaceutical ingredient customarily used. Now, in this case if we go back to the claims we already know the amount. The amount is 0.25 milligrams and -- 0.25 milligrams and 5 milliliters, so it is a 5 milliliter solution, and it is used once, and that's the amount that's needed to treat the condition we're talking about. So, if anything, Dr. Spilker's discussion of unit-dose ties in this customary use idea of what are you using it for. We're using it to treat cancer chemotherapy-induced nausea and vomiting.

So, again, point number one, defendants's matching test fails for the claim language they admit is limiting. There's nothing in here that ties single-use or unit-dose to the bodies of the claim.

And number two single-use unit-dose --

THE COURT: What they're doing is they're looking at it grammatically and saying the terms "single-use" and "unit-dose" are used as adjectives to modify the noun "formulation" as a subject, not an object of the sentence. It is not a sentence. The whole thing is not a sentence. The whole preamble is not a sentence.

MR. DITTMANN: The preamble is not a sentence, but the preamble, we would submit, describes the formulation, and let me explain why.

THE COURT: But they're saying these two adjectives in front of the noun "formulation" don't have to be stripped

off of the noun "formulation." "Said formulation" should pick up the nouns that immediately previously modify them. And you're saying, well, good, then why doesn't the word "formulation" in the preamble also pick up all of the dependent phrases that are attached at the other side of the word "formulation."

MR. DITTMANN: If you want to get into rules of grammar what this is, "for intravenous administration" is a prepositional phrase that functions as an adjective. Look it up in any grammar book. And the same applies to the rest of this. So what we have here is a series of adjectives. And they could have written this as single-use unit-dose, intravenous, cancer chemotherapy-inducing treating -- you know, it gets cumbersome after a while, and sometimes people use different ways to explain the same concept. But, again, we would submit that these are prepositional phrases that function as adjectives, and it is made crystal clear through the prosecution that these are time limitations. And if I may go to, again, the '219 patent prosecution history where the examiner was summarizing what was discussed because I do think that's important. It doesn't get much clearer, your Honor, than this. "Highlighted the limitations that were in the claims." "Cancer chemotherapy-induced nausea and vomiting."

Your Honor, again, if we were attempting -- if a patentee was attempting to say this is not a limitation of the

claim and this matter to infringement, for example, they would be the saying this is a representation, a clear representation of what's in the claims. They couldn't be any clearer.

THE COURT: I understand, but what your adversary was arguing was that the highlighting would have to be to distinguish prior art, not to highlight for purposes of being sufficiently clear, and what's the word, Section 112. I always get "enablement" and "written description" mixed up because to me they blend together. Written description, where is the pH in there is what the examiner is asking, and you say, well, we have got all this other stuff in there that makes it sufficiently definite.

MR. DITTMANN: There's a couple things on that because you raise a very good point that I wanted to address. Catalina Marketing, if you read that decision, is just a summary of previous decisions. It isn't some watermark case that established a new rule of law. In that case they talked about relying on the prosecution to distinguish the prior art surely as a way that you can transform a preamble language into a limitation. Fantasy Sports came out the same time. I was the law clerk that worked on Fantasy Sports. I know the case very well. Fantasy Sports, if you look at when the petition for rehearing was denied, it was denied after Catalina was issued, so if Catalina changed the law in any respect the Federal Circuit would have addressed that.

Putting that aside, Fantasy Sports could not be clearer that it was reliance on preamble to overcome a 112 rejection.

THE COURT: A 112?

MR. DITTMANN: 112. Transform that into a claim limitation. And, again, that's exactly what we have in our case, and going back to this point about being clear, your Honor, again, it doesn't get much clearer than the claims are directed towards reducing emesis and reducing the likelihood of emesis.

All defendants can point to is in some appeal brief they didn't mention those words in the concise summary, which, again, number one, doesn't have to address, as your Honor was alluding to, doesn't have to address every single claim element. It was discussing what was involved in that appeal. This is crystal clear. Directed towards. They did it again.

THE COURT: And they're talking there about we're going to talk about "reducing," rather than "preventing," and we're watering down our language to "reducing" to satisfy your overinclusiveness of, what is it, written description objection.

MR. DITTMANN: Right. The applicants didn't agree with the examiner, but they said let's -- we'll amend it to make you happy to overcome this rejection.

Now, I also wanted to very briefly --

THE COURT: Go on and talk about Tang because I got

quite focused on that --

MR. DITTMANN: Yes, I wanted to come back to that.

THE COURT: -- in that examiner interview.

MR. DITTMANN: So, again, it is an examiner interview, and, again, we don't think it could be any clearer that it is discussing prior art. If there was a mention in the beginning of this summary record about what about the lack of pH, you know, that could be the examiner is wondering, well, wait a minute, how are you going to distinguish this prior art if you don't have a pH limitation?

THE COURT: So, it could have been obviousness or written description?

MR. DITTMANN: And, your Honor, when it says "prior art discussed" that means they're talking about prior art, not a written description or an enablement issue.

THE COURT: Where is the word "prior art"? Oh, okay up there. Right.

MR. DITTMANN: So, very clear we're talking about overcoming the prior art. Number one.

Number two, again, the statement couldn't be clearer. There's no test of what may be the potential intent of Mr. Sullivan -- and the counsel for defendants said maybe this was a self-serving statement. That's irrelevant. What he said is what you're stuck to. The patentee makes a representation of what's in the claims. They're bound by it.

And more to your point, your Honor, again, here they highlighted this claim limitation "cancer chemotherapy-induced nausea and vomiting" and discuss Tang in the context of PONV.

THE COURT: In other words, look, we are coming out with something that addresses the cancer chemotherapy-induced condition at a very low dosage and distinguishing it from the post-op condition that has hitherto under Tang prior art required a much higher dosage.

MR. DITTMANN: And, Your Honor, you'll hear a lot about this when the parties are before you at trial.

THE COURT: But is that what they're talking about?

MR. DITTMAN: Yes, that is what they're saying.

THE COURT: They are distinguishing prior art?

MR. DITTMANN: They are distinguishing the Tang reference on a number of grounds, one of which is this is a PONV study, whereas we're talking about cancer chemotherapy nausea and vomiting in our claims.

THE COURT: So, you disagree with defendants that it is just a discussion about relative dosage amounts comparing the applicant's application with Tang's higher dosage?

MR. DITTMANN: It certainly involved that discussion of dosage amounts, but there is more than that reflected in this interview summary record, but, again, I would submit that this statement is enough. "Limitations that were in the claims." It doesn't get any clearer than that.

THE COURT: And I suppose then that as the patent holder plaintiff in this case if somebody comes along and wants to use a pharmaceutical composition for something other than CINV you would agree that it is not covered by this '219 patent, it is not infringing of the '219 patent.

MR. DITTMANN: Are you talking about an actual product that's being sold on the market?

THE COURT: I'm saying an FDA application. In other words, let me turn it around. Defendant's next to last argument was, well, the reason -- and the reason that Catalina Marketing says that these usage phrases in the preamble to a composition or apparatus patent are not generally considered to be limitations is that if you've got a composition or an apparatus then the patent holder for that gets it on the composition and the apparatus, not on the use of it. And that actually makes it a much broader patent territory covered by that patent because regardless of how the would be infringer would seek to use the thing they're still infringing because they're infringing the composition without any use limitation in the patent.

MR. DITTMANN: Let me --

THE COURT: So, you're willing to live with that, right?

MR. DITTMANN: This is not a use limitation. Again, this is a capability. So, in your hypothetical if someone was

saying I have this palonosetron formulation, and I'm selling it for some other indication, if what they're selling has the capability, the amounts, the dosage amount the way it is delivered, if it can treat CINV it infringes. It is a capability.

THE COURT: Even if they're advertising it for some other use?

MR. DITTMANN: Yes, because it is a composition claim.

THE COURT: Or getting it approved by the FDA for another use?

MR. DITTMANN: Again, there's no use limitation in this patent. It is only a capability. It is capability. The formulation has to be capable. Just like the Vizio case, which I think is analogous that counsel didn't discuss, but it is capable of being able to do something. All the structure in the formulation has to be capable of treating CINV. If it can't do that, it wouldn't be covered. But, again, it is not a use limitation.

THE COURT: What if you have a method patent for a pharmaceutical composition, and I have seen a lot of these where the method says, the method of treating a patient consisting of -- I never understand this. Getting a hold of the following five ingredients and baking them three times and distilling them and formulating them into a tablet, period.

That's supposedly a method patent. But it has got all the steps and ingredients for making the finished product. Could a method patent such as that ever be claimed to infringe a composition patent such as this '219 patent if the result of practicing the method then would be capable of having this therapeutic effect. In other words, can somebody claiming a method actually infringe a composition patent?

MR. DITTMANN: Well, I think in your hypothetical, your Honor, a method of manufacturing patent if in making the composition that's covered by our claims if they followed those steps that you laid out they would infringe both the method of making it, which is one thing, and then there's also they would then infringe the composition because what they ended up with after they have copied the method of the manufacturing is the same product that we claim in our patent.

THE COURT: Okay. Thank you. Anything else?

MR. WONG: Your Honor, can I make one point of clarification?

THE COURT: Yes.

MR. WONG: It is just on the written description issue. I wanted to make sure we're all clear. We are only -- the defendants are only asserting the written description as a defense if you interpret the disputed preamble language of the intended use as a limitation. To the extent you say that it is not a limitation, as we have argued, then we won't have a

written description defense. Just to be clear.

THE COURT: I understand.

MR. WONG: Thank you.

THE COURT: Okay. Great. Okay. I think we have aired this. Anybody else over there suffering?

MR. D'AMORE: No. Thank you, your Honor.

THE COURT: Mr. Wong, you carried your side completely. Thank you all for coming. I'm not going to rule from the bench.

(Proceedings concluded at 3:40 p.m.)

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